

Evolut Clinical Guideline 2742.CC for Skin Substitutes for Wound Management

Guideline Number: EVH_CG_2742.CC	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all members receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines, and state/national recommendations.*
- *Any skin substitute not outlined in this policy is considered unproven or experimental and investigational but may be subject to clinical review.*

Purpose

The purpose of this policy is to define the appropriate use of **skin substitutes for wound management** when any one of the following conditions are present:

- Diabetic Foot Ulcers (DFU): Full-thickness neuropathic ulcers ≥ 1.0 cm² that have not healed after at least 4 weeks of standard care, including offloading, infection control, debridement, limb elevation, and proper dressings.
- Venous or Pressure Ulcers (VPU) or Vascular Leg Ulcers (VLU): Chronic nonhealing wounds that fail standard therapy.
- Burns: Second- and third-degree burns where autografts are insufficient or unavailable.
- Post-Surgical Reconstruction: Breast reconstruction or other surgical wounds where skin coverage is inadequate, particularly in patients with compromised healing.
- Primary Dermatologic Conditions: Large areas of skin breakdown, such as bullous diseases, when standard care is insufficient.

Definition

Skin substitutes are bioengineered, biological, or synthetic materials designed to replace or repair damaged skin, providing temporary or permanent coverage and promoting tissue regeneration. Skin substitutes provide a three-dimensional scaffold to replace extracellular matrix, support attachment/migration/proliferation of host or seeded cells, deliver or augment growth factors and cytokines, and protect from mechanical trauma, infection, and fluid loss.

They are broadly categorized into:

- Epidermal substitutes: Replace the outermost skin layer
- Dermal substitutes: Replace the deeper dermal layer
- Composite substitutes: Combine both epidermal and dermal layers for comprehensive coverage

Key Types of Skin Substitutes

- Acellular Skin Substitutes
 - Composed of extracellular matrices without living cells
 - Widely used for chronic wounds, burns, and surgical applicationsExamples: Integra Dermal Regeneration Template
- Cellular Allogeneic Substitutes
 - Contain donor-derived living cells to promote tissue regeneration
 - Used for complex wounds and burnsExamples: Apligraf (Organogenesis), Dermagraft (Organogenesis)
- Synthetic Skin Substitutes
 - Made from biomaterials such as silicone, collagen, or polymers
 - Provide temporary or permanent wound coverageExamples: Dermagraft-TC
- Composite Skin Substitutes
 - Combine biological and synthetic components for enhanced healing
 - Offer structural support and cellular activityExamples: Integra Bilayer Wound Matrix

POLICY

Overview

It is the policy of CountyCare Health (CountyCare) to apply available criteria and nationally recognized guidelines when making medical necessity review determinations for the use of skin substitutes. Any new skin substitutes/procedure codes that are added to current fee schedules will be covered under this policy, will require prior authorization and follow the requirements of this policy.

Skin substitutes are advanced wound therapies used when standard of care (SOC) alone fails to promote healing in chronic or hard-to-heal wounds. They are typically indicated for wounds that do not close or reduce in size by about 40–50% within 4 weeks of SOC treatment

Skin substitutes are indicated as an adjunct to conventional treatments in chronic, non-healing wounds.

Criteria for Using Skin Substitutes

Skin substitutes may be considered when chronic wounds do not show improvement after at least four (4) weeks of standard wound care. Documentation must indicate that the wound has

not failed to reduce by 40% in size or depth (using conventional treatment) and has shown no signs of healing, such as granulation or epithelialization.

Skin substitutes are indicated for the treatment or management of chronic and hard-to-heal wounds including failure of SOC.

Before considering a skin substitute, a SOC treatment plan includes:

- **Wound assessment** (etiology, size, depth, infection status)
- **Infection control** (cultures, antibiotics if indicated)
- **Debridement** of necrotic tissue
- **Moist wound environment** (non-adherent, hydrocolloid, foam, alginate, hydrofiber, hydrogel dressings)
- **Vascular and metabolic optimization** (blood sugar control, vascular assessment)
- **Mechanical offloading** (offloading devices for DFUs)
- **Compression therapy** for venous ulcers
- **Tobacco cessation** and management of other comorbidities

Key Contraindications

- **Active Infection:** The presence of infection in the wound bed must be treated before considering a graft.
- **Allergic Reactions:** Patients with known allergies to materials used in the graft (e.g., collagen, bovine or porcine derivatives) should avoid specific products.
- **Poor Vascularization:** Wounds with insufficient blood supply may not support the integration and survival of the graft.
- **Systemic Conditions:** Patients with uncontrolled diabetes, severe malnutrition, or other systemic conditions that impair healing may not be good candidates for skin substitute grafts.
- **Issues affecting compliance** such as dementia, involuntary motor diseases or provider concerns regarding the patient's ability to comply with care.
- **Known or suspected malignancy** of the ulcer
- **Active deformity** or major structural deformity that can compromise wound healing and increase risk of complications.
- **Ulcer not extended** to tendon, muscle, capsule, or bone as too superficial for effective coverage and/or healing

PROCEDURE

Initial Documentation Requirements

The following are required in advance to complete a medical necessity review:

- Patient Factors:
 - Confirmation of the patient's overall health, including comorbidities (e.g., diabetes, vascular disease), is essential
 - Medical Provider Management: Confirmation that member is under the care of a qualified provider managing the underlying systemic disease (e.g., venous insufficiency, diabetes, neuropathy) and includes comprehensive patient assessment (history, exam, vascular assessment) and diagnostic tests as indicated as part of the implemented treatment plan
 - Smoking: if a smoker, documentation that attempts at smoking cessation- medication and/or counseling
- Confirmed completion of SOC treatment plan as noted above
- Additionally for the following types of wounds further details regarding assessments should be included as follows:
 - For DFUs: assessment of Type 1 or Type 2 diabetes and management history with attention to comorbidities, review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion and assessment of off-loading devices or use of appropriate footwear
 - For VLU: Assessment of clinical history, including prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies and physical inactivity, physical exam (edema, skin changes and vascular competence), evaluation of venous reflux, perforator incompetence and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing is an essential component of SOC for venous stasis ulcers
- Post completion of SOC Wound Management-Type of wound, status of wound- pre-treatment measurements and measurements following at least four weeks of SOC treatment

Ongoing Documentation Requirements

The following ongoing documentation is required to consider concurrent approval:

- Treatment goals should be reviewed and progress assessed as treatment continues.
- Provision of wound improvement, which includes the following milestones towards achieving a successful outcome may include:
 - No clinical signs of acute infection
 - Formation of granulation tissue

- Re-epithelialization
- Reduction in wound size
- Successful removal of the method of attachment (i.e. staples, sutures or wound closure strips)

LIMITATIONS

- Maximum Applications: Up to eight applications within a 12–16-week episode of care, with strict documentation requirements justifying more than four applications.
- Repeat applications are not reasonable and necessary when a previous application was unsuccessful, which is defined as increase in size or depth of an ulcer, no measurable change from baseline and no sign of improvement or indication that improvement is likely such as granulation, epithelialization or progress towards closures. This requires close oversight.
- Application is not reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, or ischemia).

CODING AND STANDARDS

Codes

The following codes are not inclusive of all codes that may require prior authorization. Any new skin substitute procedure code added via Illinois Healthcare and Family Services (HFS) or the Enhanced Ambulatory Patient Grouping (EAPG) will require prior authorization.

Code	Description
Q4101	Apligraf, per sq cm (add-on, list separately in addition to primary procedure)
Q4102	Oasis wound matrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4103	Oasis burn matrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm (add-on, list separately in addition to primary procedure)

Code	Description
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4107	GRAFTJACKET, per sq cm (add-on, list separately in addition to primary procedure)
Q4108	Integra matrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4110	PriMatrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4111	GammaGraft, per sq cm (add-on, list separately in addition to primary procedure)
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq cm (add-on, list separately in addition to primary procedure)
Q4116	AlloDerm, per sq cm (add-on, list separately in addition to primary procedure)
Q4121	TheraSkin, per sq cm (add-on, list separately in addition to primary procedure)
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm (add-on, list separately in addition to primary procedure)
Q4124	OASIS ultra tri-layer wound matrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4132	Grafix Core and GrafixPL Core, per sq cm (add-on, list separately in addition to primary procedure)
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm (add-on, list separately in addition to primary procedure)
Q4151	AmnioBand or Guardian, per sq cm (add-on, list separately in addition to primary procedure)

Code	Description
Q4154	Biovance, per sq cm (add-on, list separately in addition to primary procedure)
Q4159	Affinity, per sq cm (add-on, list separately in addition to primary procedure)
Q4160	NuShield, per sq cm (add-on, list separately in addition to primary procedure)
Q4186	Epifix, per sq cm (add-on, list separately in addition to primary procedure)
Q4187	Epicord, per sq cm (add-on, list separately in addition to primary procedure)
Q4191	Restorigin, per sq cm (add-on, list separately in addition to primary procedure)
Q4195	PuraPly, per sq cm (add-on, list separately in addition to primary procedure)
Q4196	PuraPly AM, per sq cm (add-on, list separately in addition to primary procedure)
Q4197	PuraPly XT, per sq cm (add-on, list separately in addition to primary procedure)
Q4271	Complete FT, per sq cm (add-on, list separately in addition to primary procedure)
Q4326	WoundPlus, per sq cm (add-on, list separately in addition to primary procedure)

Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

POLICY HISTORY

Date	Summary
April 28, 2026	New Policy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members’ health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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